

ALLEGED SHIPMENT: From Pasadena, Calif., by Therapy, Ltd. The drug was shipped between the approximate dates of April 21 and May 1, 1944, and the display cards and booklets were shipped in November 1943.

PRODUCT: 178 bottles of *Theradophilus* at Denver, Colo., together with a number of display cards entitled "Theradophilus" and a number of booklets entitled "Therapy Supplementary Foods." Samples of the article were found to contain viable acidophilus in amounts varying from 100,000 to 5,100,000 per cubic centimeter and bacteria other than acidophilus in amounts varying from 280,000 to 7,200,000 per cubic centimeter.

LABEL, IN PART: "Theradophilus A Condensed Pure Culture of Bacillus Acidophilus."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity of the article fell below that which it was represented to possess, in that it was represented to be a "Pure Culture of Bacillus Acidophilus," whereas it was not a pure culture of bacillus acidophilus, but was a culture of bacillus acidophilus contaminated with foreign micro-organisms.

Misbranding, Section 502 (a), the following labeling statements were false and misleading as applied to the article, which contained cocci and short-rod forms of bacteria: (Bottle label) "Theradophilus A condensed Pure Culture of Bacillus Acidophilus"; (display cards) "Theradophilus Acidophilus Culture"; (booklet) "A Vigorous Culture of Acidophilus."

Further misbranding, Section 502 (a), certain statements in the display cards and booklets were false and misleading since they represented and suggested that the article would be effective as a remedy for colitis, diarrhea, dysentery, constipation, hyperacidity, excessive gas, and auto-intoxication; that it would be effective in overcoming putrefaction resulting from overindulgence in food, constipation, diarrhea, toxic headaches, dullness, loss of energy, many diseases, and premature death; that it would be effective for controlling conditions in the intestines; that it would be effective in safeguarding against intestinal poisoning; that it would be conducive to longevity; that it would be effective in enabling one whose strength had been pulled down by harmful bacteria to regain the clear eyes and sparkling energy of youth; and that it would be effective to accomplish great improvement in health. The article would not be effective for the purposes represented.

DISPOSITION: August 4, 1944. No claimant having appeared, judgment of condemnation was entered and the product, together with the printed matter, was ordered destroyed.

1817. Adulteration and misbranding of Mennen Antiseptic Oil. U. S. v. 51 Packages of Mennen Antiseptic Oil. Consent decree of condemnation. Product ordered disposed of for industrial purposes. (F. D. C. No. 11288. Sample No. 56392-F.)

LABEL FILED: December 10, 1943, Eastern District of New York.

ALLEGED SHIPMENT: On or about July 15, 1943, by the Mennen Co., from Newark, N. J.

PRODUCT: 51 packages, each containing 1 gallon, of *Mennen Antiseptic Oil* at Long Island City, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, in that it was represented to be germicidal and self-sterilizing, whereas it was neither germicidal nor self-sterilizing.

Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since the article was not germicidal, was not self-sterilizing, and was not efficacious for the symptoms and conditions mentioned: "Germicidal * * * Self-Sterilizing * * * It is so medicated as to make the oil * * * germicidal * * * self-sterilizing. * * * It has greater antiseptic and germicidal powers than the commonly used ammoniated mercury ointments. * * * The Oil is self-sterilizing, and autoclaving is not necessary. * * * It helps kill and prevent the growth of pyogenic organisms as long as it is in contact with the skin. * * * It helps maintain and conserve vital body temperature. It helps sterilize * * * the diaper area. * * * Meets the widespread demand of hospitals, physicians, nurses and mothers * * * germicidal * * * and self-sterilizing oil * * * offers protection against infection * * * Mennen Antiseptic Oil aids in keeping the skin of the babies free from pyogenic organisms. * * *

quickly relieves * * * aggravated skin conditions. Prescribed where * * * germicidal oil dressing is required."

DISPOSITION: On October 30, 1945, the Mennen Co., claimant, having filed an answer denying the allegations of adulteration and misbranding set forth in the libel, the case came on for trial before the court without a jury. On October 31, 1945, after the court had heard part of the proof of the Government, the claimant consented to the entry of a decree of condemnation. A decree was accordingly entered on November 13, 1945, condemning the product, and on May 3, 1946, an order was entered providing for the mixing of the product with other fats for industrial purposes, under the supervision of the United States marshal.

1818. Adulteration of Peptulcyl Proteolytic Enzymes. U. S. v. 40 Ampuls and 88 Ampuls of Peptulcyl Proteolytic Enzymes. Default decrees of condemnation and destruction. (F. D. C. Nos. 17122, 17263. Sample Nos. 7014-H, 20292-H.)

LIBELS FILED: August 17 and 31, 1945, District of New Jersey and Northern District of Oklahoma.

ALLEGED SHIPMENT: On or about April 10 and July 19, 1945, by the Solex Laboratories, Inc., from Brooklyn and New York, N. Y.

PRODUCT: 40 ampuls and 88 ampuls of *Peptulcyl Proteolytic Enzymes* at Hoboken, N. J., and Tulsa, Okla., respectively. This product was intended for parenteral use and was not sterile, as is required for such purpose.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess, since it was unsterile.

DISPOSITION: September 10 and December 3, 1945. No claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1819. Adulteration of glucose injection, sodium iodide, and Bethiamin. U. S. v. 13 Ampuls of Glucose Injection, 50 Ampuls of Sodium Iodide, and 72 Ampuls of Bethiamin. Default decree of forfeiture and destruction. (F. D. C. No. 17073. Sample Nos. 21734-H, 21736-H to 21738-H, incl.)

LIBEL FILED: On or about August 6, 1945, Western District of Missouri.

ALLEGED SHIPMENT: Between the approximate dates of August 25, 1944, and May 25, 1945, by the S. E. Massengill Co., from Bristol, Tenn.

PRODUCT: 13 ampuls of *glucose injection*, 50 ampuls of *sodium iodide*, and 72 ampuls of *Bethiamin* at Kansas City, Mo.

LABEL, IN PART: (Ampuls) "50 cc. Size Injection Glucose (Dextrose, U. S. P.)," "10 cc. Size Sodium Iodide * * * Intravenous," or "30 cc. Size Bethiamin 33330 A brand of Thiamin Hydrochloride (B₁ * * * For Intramuscular or Intravenous Administration."

NATURE OF CHARGE: *Glucose injection.* Adulteration, Section 501 (b), the article purported to be and was represented as "Dextrose Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not free of undissolved material, as is required by the Pharmacopoeia.

Sodium iodide. Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Iodide," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality fell below the official standard since it was not substantially free of undissolved material, as is required by the Formulary.

Bethiamin. Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since it was represented for intramuscular or intravenous administration and was not substantially free of undissolved material, as is required for such purposes.

DISPOSITION: September 6, 1945. No claimant having appeared, judgment of forfeiture was entered and the products were ordered destroyed.

1820. Adulteration of phenolsulfonphthalein. U. S. v. 118 Cartons of Phenolsulfonphthalein. Default decree of condemnation and destruction. (F. D. C. No. 9750. Sample No. 44070-F.)

LIBEL FILED: April 5, 1943, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about February 25, 1943, from Brooklyn, N. Y., by the Pro-Medico Laboratories, Inc.